Alpha-Stim® AID Owner's Manual

cranial electrotherapy stimulator

ALPHA-STIM®

experience life...AGAIN™

Alpha-Stim® AID

Cranial Electrotherapy Stimulator
For Control of Anxiety, Insomnia and Depression

OWNER'S MANUAL

Type BF Equipment. This stimulator is internally powered only.

See instructions for use. Read this manual thoroughly before using the device. Do not plug lead wires into wall sockets or line cord receptacles under any circumstances. Doing so could result in severe shock or burns whether the lead wires are attached to the stimulator or not.

Medical Electrical Equipment classified by Underwriters Laboratories Inc.® with respect to electric shock, fire, mechanical and other specified hazards only in accordance with UL-60601-1 and CAN/CSA C22.2 No. 601.1. 34VF.

Conformity Statement for Europe: Alpha-Stim® AID is a Class IIa, Type BF medical device. It has been independently tested by outside agencies in order to provide assurance of conformity to applicable standards for medical equipment safety and electromagnetic compliance.

When the end-user wishes to discard this product, it must be sent to separate collection facilities for recovery and recycling. By separating this product from other household-type waste, the volume of waste sent to incinerators or land-fills will be reduced and natural resources will thus be conserved.

Caution Statement for United States: Federal law (USA only) restricts this device to sale by, or on the order of a licensed health care practitioner. Outside the USA it is available worldwide without a prescription but consultation with a qualified health care professional is recommended for difficult and unresponsive problems or when used with pharmaceuticals or other therapeutic intervention.

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FEATURES

The Alpha-Stim® AID comes complete and ready to use with 1 set of Earclip electrodes, 1 15-ml bottle of Alpha Conducting Solution™ (250-ml refill bottles available), 256 Earclip Electrode Pads (EEPS), Illustrated Owner's Manual, Lanyard, Storage Case, and 2 AAA batteries. This is everything you need to begin to use your new Alpha-Stim® AID. Replace Alpha Conducting Solution™ and EEP electrodes only with authorized Alpha-Stim® brand products.

Alpha-Stim® AID features include:

1. Full digital control for precision, consistency and reliability.
2. Earclip electrodes.
3. Back lighting when any button is pressed.
4. Continuous circuit check when electrodes are in contact with skin.
5. Preset to 0.5 Hz.
6. 20, 40 or 60 minutes countdown cycles to auto-off.
7. Large timer display.
8. 0 – 500 microampere (μA) current control.
9. Current and treatment time may be locked to preset values throughout entire treatment session.
10. Mute option.
11. Cumulative timer.
12. 30 minute auto-off when not in use.
13. Lanyard so AID can be worn around the neck.
14. Able to withstand electrostatic discharges of up to 6,000 volts.
15. Automatically and permanently disables itself should a single fault develop within the device causing the current to exceed 700 μA.
16. Uses 2 AAA 1.5 volt batteries (included).
17. Battery strength indicator.
18. Earclip Electrode Pads (EEPS) requires Alpha Conducting Solution™ (included).
19. 5 year limited warranty.

A Note to Health Care Practitioners

Thank you for recommending the Alpha-Stim® AID. This manual is written for the person who will use the Alpha-Stim® AID, but your input will be invaluable to your patient. Electromedical Products International, Inc. is available to help serve the needs of your patients. New research is often available that may have a direct bearing on a patient's specific disorder. Feel free to write, call, fax, or email EPI for any reason at all. Also, check the website regularly for new information. We welcome your input in the form of testimonial letters or emails and participation in the forums on our website.

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CONTROL BUTTONS

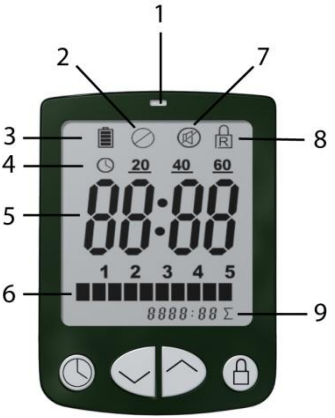
1. **On - Off**

2. **Timer**. Waveform cycle starts when electrodes touch skin. Countdown timers: select 20, 40 or 60 minutes.

3. **Lock**. Press 2 times within 5 seconds to lock or unlock settings during treatment if desired.

4. or **Current**. Increases or decreases current. Increases at 50 microamperes (µA) per second when held down. Decreases at 100 µA per second. When the device is turned on, the current defaults to 100 µA.

LCD DISPLAY



1. **Light Sensor** lights LCD screen for 10 seconds in a dark room when any button is pushed.

2. **Test Circuit** symbol and an audio warning indicates device is not treating. The timer will stop and the device will turn off in 30 minutes if nothing else is done. Current must be set above 0 µA and moistened electrodes must be in contact with skin for Alpha-Stim® AID to work. An audible signal and resumption of the timer occurs the instant the integrity check circuitry determines everything is working properly.

3. **Battery Charge** indicator. Replace battery when only 1 bar remains at which time the device shall give out an audible low battery warning and repeat the warning every 10 minutes (unless mute function is on).

4. **Timer**. Select 20, 40 or 60 minutes countdown to auto-off.

5. **Time** setting indicator. Displays time remaining.

6. ■■■■■■■□□□ 0 - 500 microamperes (µA) of current.

7. **Mute** feature. To turn on or off press the key sequence: **Lock-Timer-Lock**.

8. **Lock** is on when display is lit.

9. **Σ Cumulative Timer** records total hours and minutes Alpha-Stim® AID has been in use.

INTRODUCTION

Congratulations on your selection of the Alpha-Stim® AID Cranial Electrotherapy Stimulation (CES) device. You have purchased a quality medical device. In so doing, you have already taken the first step to a more comfortable life.

Electromedical Products International, Inc. (EPI) is a leading innovator of the finest state-of-the-art medical technology available to improve the quality of your life. EPI and its distributors are dedicated to helping those who use our products. We have technical experts available to assure you receive the best possible results from treatment. Telephone consultations in English may be scheduled with you or your doctor Monday through Friday, 9 AM until 5 PM, Central Time (Texas, USA). You may also communicate with us by mail, fax, or email. The company stands behind all our medical devices with a 5 year limited warranty.

The Alpha-Stim® AID is a precision medical device used for the management of anxiety, insomnia and depression. After treatment, there are usually no physical limitations imposed so you can resume normal activities. The treatment is simple and easy to self-administer at any time. People using the Alpha-Stim® AID usually report a pleasant, relaxed feeling of well-being.

The current is applied by Earclip electrodes for anxiety, insomnia and depression. During a treatment you may experience a mild tingling sensation at the electrode sites. If the current is too high, you might experience dizziness and nausea which can both be alleviated by reducing the current.

Once you understand the basic product features and procedures you will find the Alpha-Stim® AID is easy to use. Please read this entire manual thoroughly before using it. Be sure to follow the general instructions given herein and any specific directions from your health care practitioner.

DESCRIPTION

Results in electromedicine are based on the design of the waveform, the amount of current, the location of the electrodes, and the amount of time it is used. The Alpha-Stim® AID is a microcomputer incorporating the latest advances in solid state electronics. All components are of the highest quality available to assure the user reliable and trouble-free performance.

The design assures electrical safety by the use of readily available 1.5 volt AAA batteries.

The Alpha-Stim® AID was developed through original research by Electromedical Products International, Inc. It is a precision technology which generates a modified square, bipolar waveform of 0.5 Hz (pulses per second), at 50 to 500 microamperes (1 μA is one-millionth of an ampere), in a 50% duty cycle.

The Alpha-Stim® AID is small, compact and light-weight. It was designed to be versatile. It can be used in a health care practitioner's office, clinic or hospital, for portable and quick response needs such as emergency medical or military applications, as well as for self-administered treatment at home on a scheduled or as-needed basis.

The controls are fully digital for precision, consistency and reliability and at the same time simple and easy to operate. An adjustable timer and a locking option that freezes the treatment time and current settings assures the prescribed treatment waveform and dosage even if you are distracted or fall asleep. The amount of current can easily be increased to reduce treatment time or decreased when necessary to assure comfort.

One important feature of the Alpha-Stim® AID is an electronic circuit which operates to maintain a nearly constant current flow to the electrodes minimizing the effects of skin resistance variations. The Alpha-Stim® AID continuously performs self-diagnostics to assure that all aspects of the circuitry are always working properly and the electrodes are making adequate contact with skin. Ergonomic and user-friendly features (such as the lock, auto-off timers and alarm that warns you if an electrode falls off) make the Alpha-Stim® AID reliable, easy, quick, and fun to use.

The Alpha-Stim® AID was developed by neurobiologist, Dr. Daniel L. Kirsch and engineer, Raymond Chan. Dr. Kirsch has been a leading pioneer

in the field of electromedicine since 1972. He was board-certified in pain management by the American Academy of Pain Management in 1990, and awarded the Richard S. Weiner Pain Educator of the Year Award by AAPM in 2008. He became a Fellow of the American Institute of Stress in 1997. He is also a Member of Inter-Pain, the organization for pain physicians in Germany and Switzerland. He is the Electromedical Department Editor of the journal, *Practical Pain Management* and a Consulting Editor for the *Journal of Neurotherapy*. Dr. Kirsch has served as Clinical Director of the Center for Pain and Stress-Related Disorders at Columbia-Presbyterian Medical Center in New York City and the Sports Medicine Group in Santa Monica, California. He is an author of books and articles and lectures frequently to physicians and psychologists worldwide on pain and stress management and is an expert research and practice consultant to Veterans Affairs Medical Centers and the United States Army.

ELECTROMEDICAL THERAPEUTICS

The application of electromedical currents is not a new concept. Ancients recognized the therapeutic value of naturally occurring electrical phenomena long before William Gilbert defined electricity in 1600. Both Aristotle and Plato referred to the Black Torpedo (electric ray fish) prescribed in 46 AD by the physician Scribonius Largus for the relief of a variety of medical conditions from headaches to gout (head to foot). In the 1800s dentists reported pain reduction using early and somewhat crude electromedical devices.

By the late 1800s electrical devices were in widespread use to manage pain and claimed to cure a variety of medical disorders. The exuberant claims of early electrical technologies facilitated by the political clout of the pharmaceutical lobbies caused this form of therapy to fall into disrepute by the medical profession in the early part of the 20th century. As a result medical colleges stopped teaching electrotherapeutics. Biophysics was virtually eliminated from medical practice leaving chemistry as the master science and with it the burden of responsibility for curing all disease. Now, in the 21st century, it is clear that chemistry as the sole therapeutic model for medicine has not lived up to its promise, causing

modern medicine to re-examine the potential of biophysics.

Experimentation with low intensity electrical stimulation of the brain was first reported by Drs. Leduc and Rouxeau of France in 1902. Initially, this method was called electrosleep as it was thought to be able to induce sleep. Research on using what is now referred to as Cranial Electrotherapy Stimulation (CES) for treatment of anxiety, insomnia and depression began in Russia during the 1950s and first came to the USA in the 1960s.

All life is of an electrochemical nature. There are extensive electrical fields at work throughout the universe and the body. The nervous system, for example, has long been known to work through both electrochemical and purely electrical signals. In fact, all molecules are held together by electrical bonding at the atomic level. Basic science research into the nature of bioelectrical control systems in humans and animals led medical scientists such as Dr. Robert O. Becker of the USA[1] and Dr. Björn Nordenström of Sweden[2] (who served as Chairman of the Nobel Assembly) to propose completely new theories of physiology based on our latest understanding of biophysics.

Alpha-Stim® technology incorporates these theories and is proven more efficacious than most other treatments for the conditions it treats. The original Alpha-Stim® Model 2000 weighed 40 pounds and cost $5,850 when it was first introduced in 1981. The Alpha-Stim® AID utilizes the most advanced technology available today. It is now possible, in most cases, to alleviate anxiety, insomnia and depression with far less current than used in previous technologies, and experience long-term and cumulative relief with as little as only 20 minutes of treatment every other day. When used properly, we trust your new Alpha-Stim® AID will improve the quality of your life.

[1] Becker, Robert O. *The Body Electric*. New York: William Morrow and Co. 1985.

[2] Nordenström, Bjorn E.W. *Biologically Closed Electric Circuits*. Stockholm: Nordic Medical Publications, 1983.

USE THE ALPHA-STIM® AID WITH CONFIDENCE

Because the Alpha-Stim® AID uses such a low level of current, many people do not feel anything at all, even at the maximum current level. Do not be concerned if you can not feel the current; this is perfectly normal and your perception of the current will not affect the results. The Alpha-Stim® AID is working unless the ⊘ **Test Circuit** symbol appears or the low battery indicator is down to the last bar. Some people only achieve maximum benefits when using the Alpha-Stim® AID for hours every day. While this is rarely necessary it is also not harmful – so use the Alpha-Stim® AID with confidence knowing you have a safe and effective tool to help you *experience life…AGAIN*™.

Quick Guide

Read the following instructions carefully. Then, after you have used the Alpha-Stim® AID once you simply press the *Power* button, wet the electrodes on the *Earclips*, place them on both ear lobes and adjust the current to a comfortable level. *That's all there is to it!* Readjust the current up or down to a comfortable level at any time during treatment if necessary.

Cranial Electrotherapy Stimulation (CES) To Treat Anxiety, Insomnia and/or Depression with Earclip Electrodes

1. Clean ear lobes with mild soap and water, alcohol pads or antibacterial wipes and allow skin to dry. Areas where skin oils or dirt have accumulated, or where cosmetics or hair spray have been used must be thoroughly cleaned to ensure adequate conductivity. Monitor skin condition prior to and after treatment. Skin irritation may develop in light skin. If skin burns are noted following treatment, discontinue use and apply an appropriate skin cream. Varying **Earclip** locations around the ear lobe may minimize irritation.

2. Plug dual connector end of **Earclip** wires into jack on left side of the Alpha-Stim® AID. **Figure 1**.

3. Remove and discard old **Earclip Electrode Pads (EEPS)** if present. Remove old glue residue, clean and dry Earclips and attach 4 new **EEPS**. Note that **EEP** case opens with label on bottom.

4. Saturate 4 new **Earclip Electrode Pads (EEPS)** thoroughly with several drops of **Alpha Conducting Solution™ (ACS)** while on Earclip electrodes.

5. Press **Power** on.

6. **Mute** the audio, if desired, with the key sequence: **Lock-Timer-Lock**. To reinstate the audio alerts press the same key sequence again.

Figure 1

7. Set **Timer**. 20 minutes is usually enough time if the current is set to at least 250 µA. 40 minutes to 1 hour is recommended if the current is at or below 200 µA.

8. Squeeze **Earclips** and apply one to each ear lobe. **Figure 2**.

Figure 2

9. **Current** defaults to 1 (100 µA) when the Alpha-Stim® AID is turned on. Increase **Current** slowly (5 is the highest setting) until a slight vertigo is experienced (a dizzy feeling, similar to the sensation of rocking on a boat), then decrease *immediately* until the dizziness stops. Also decrease immediately if the normal tapping sensation felt on the ear lobes is uncomfortable. For people who have a history of experiencing vertigo such as motion sickness, treat at a subsensory current setting of 1 (100 µA) for one hour or more to prevent residual vertigo after treatment. The tolerable current level will be determined by the subjective feeling of vertigo which should subside immediately upon reducing the current. The current should always be reduced just below the level that causes vertigo.
10. Press **Lock** twice to lock settings, if desired. Press **Lock** twice again to unlock and change settings, if necessary.
11. Relax, if possible, during the treatment. It is best to sit quietly or lie down although it is also possible to read, work at a desk or watch television during treatment. Do not attempt to drive or operate any dangerous tools or machinery during treatment.
12. **Power** will turn off automatically at the conclusion of the timed cycle.
13. **Always complete a CES session.** When the timed session ends, and a "heavy" feeling is still experienced, resume treatment until at least 2 minutes after the heaviness lifts and a light feeling develops. Failure to do this can result in disorientation that can last for hours to days. Some people benefit the most from several hours of treatment in a given treatment session.
14. Remove and discard **EEPS**. Clean and dry **Earclips** and replace 4 **EEPS** for the next treatment, if desired. **EEP** case opens with label on bottom.

15. Store Alpha-Stim® AID away from children.

16. CES may be used as often as necessary but for most people it is best to treat between once a day and twice a week. Results usually improve and last longer with additional treatments.

WHAT TO EXPECT

While the Alpha-Stim® AID is significantly effective when it is used correctly for 9 out of 10 people who use it, it will not work for everyone. If the Alpha-Stim® AID is not working well for you contact your health care practitioner, your local authorized Alpha-Stim® distributor or EPI for technical support.

Anxiety reduction is usually experienced during a single treatment, but may be experienced hours after treatment.

Insomnia is usually improved after the initial treatment but may take 3 weeks. Most people can use it at bedtime and when awakened during the night. However, some people find they must conduct their 20 - 60 minute Alpha-Stim® CES treatment at least 3 hours before going to bed because a CES treatment may interfere with sleep. It may also be used in the morning to promote better sleeping at night.

Depression typically takes 3 weeks or more of daily treatment to experience significant improvement, but may take considerably longer. After the condition is under control, use of Alpha-Stim® 2 - 3 times per week or less is usually sufficient to maintain good results.

Following treatment, there are usually no physical limitations imposed so most users can resume normal activities immediately. Some users may have a response that may affect their ability to perform potentially hazardous tasks, such as operating a motor vehicle or heavy machinery for up to several hours after treatment.

At present, there are over 150 research studies on using Cranial Electrotherapy Stimulation in humans and more than 30 animal studies. No significant lasting side effects have been reported. Occasional headache, discomfort or skin irritation under the electrodes or lightheadedness may occur. If a heavy feeling occurs, continue treatment until at least 2 minutes after it gives way to a light feeling. These are all mild, self-limiting reactions.

PRESCRIBING INFORMATION

EPI is ISO Certified

Electromedical Products International, Inc. is an International Standards Organization (ISO) certified establishment. ISO is an International organization working with some 140 countries and the United Nations to maintain standards for all applications of technology for global industry. Requirements for the medical device industry relate to design controls, risk management, environmental controls, special processes (*e.g.* software validation), traceability, record retention, and regulatory actions such as vigilance.

Electromagnetic Interference

This equipment has been independently tested by outside agencies and found to comply with the limits of Comité International Spécial des Perturbations Radioélectriques (CISPR). These limits are designed to provide reasonable protection against harmful interferences in a residential or clinical environment. However, it is still possible that interference could occur in a particular environment. In case interference does occur, increase the distance between this device and the equipment it interferes with. Consult Electromedical Products International, Inc. if the problem persists.

CE Conformity Statement for Europe

The Alpha-Stim® AID is a Class IIa, Type BF medical device. It has been independently tested by outside agencies to provide assurance of conformity to applicable standards for medical equipment safety and electromagnetic compliance.

Caution Statement for United States

Federal law (USA only) restricts this device to sale by, or on the order of, a licensed health care practitioner. Outside of the USA it is available worldwide without a prescription but consultation with a qualified health care practitioner is recommended.

Indications

Alpha-Stim® AID is an effective treatment for the management of anxiety, insomnia and depression, or for the short term relief of the symptoms associated with these indications. In many cases it is the sole therapeutic method required. As with any therapeutic intervention, not all people will respond to the Alpha-Stim® AID. The degree of efficacy will vary with the nature of the problem being treated, the overall health of the person, and with the method of treatment. As much as a one month initial trial may be required to see significant reductions in symptoms.

Contraindications

The Alpha-Stim® AID may affect the operation of implanted demand type cardiac pacemakers and implanted defibrillators.

Precautions

For external use only. Do not allow children to use or handle this device without adult supervision. Do not operate potentially dangerous machinery or vehicles during treatment and in some cases for several hours after treatment. Safety of stimulation has not been established during pregnancy.

Adverse Effects

Adverse effects are usually mild and self-limiting. Adverse effects from data on approximately 8,792 patients participating in 144 controlled studies, open clinical trials, and uncontrolled conditions, and by physician survey and reasonably associated with the use of CES are dizziness (6 cases, 0.07%), skin irritation/electrode burns (6 cases, 0.07%), and headaches (9 cases, 0.10%). Prolonged CES treatment at currents higher than necessary may cause dizziness or nausea that can last for hours to days. Treatment immediately prior to going to sleep may cause difficulty sleeping. Paradoxical reactions such as increased anxiety, and sleep disturbances may occur, but are rare.

If the Alpha-Stim® AID does not begin to control your anxiety, insomnia or depression within one month consult your health care practitioner, authorized Alpha-Stim® distributor, or EPI.

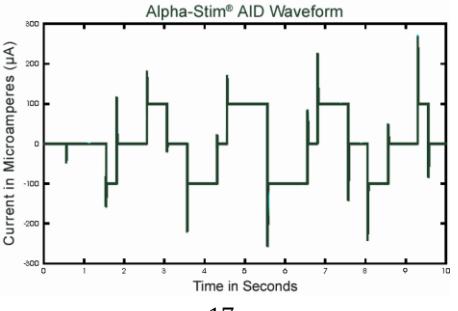
TECHNICAL SPECIFICATIONS

Electrical

Batteries	2 AAA 1.5 volt (included). Replace with disposable batteries. Do not use rechargeable batteries. Dispose of batteries safely in accordance with local government regulations.
Timer	20, 40 or 60 minute countdown timers.
Current	0 to 500 microamperes (μA) adjustable in 50 μA increments.
Frequency	0.5 Hz (pulses per second) combined with a constant 0.4 Hz. The average pulse repetition rate is 0.8 Hz.
Pulse Widths	Varying between 0.25, 0.5, 0.75 and 1 second.
Charge Per Pulse	At 500 μA the charge per pulse varies between 125, 250, 375 and 500 microcoulombs (μC). Every 10 seconds the total charge is 1.25 millicoulombs (mC) in each direction.
Waveform	The impedance range within which the waveform parameters remain valid are from 100 Ω to 10 KΩ. The waveform is composed of bipolar asymmetric rectangular waves at a 50% duty cycle repeating periodically at 10 second intervals. The waveform is balanced to achieve 0 net current in either direction (see graphic).

Mechanical

Height	9.8 cm
Width	6.3 cm
Depth	2.0 cm
Weight	101 gm with batteries



Storage and Cleaning

Remove the batteries when storing the Alpha-Stim® AID for an extended time of more than one month. Use the case to store and transport the Alpha-Stim® AID. The Alpha-Stim® AID and its accessories should be stored and used within a temperature range between 0° and 36° C, with a relative humidity below 90%, at an atmospheric pressure between 912 to 1115 hPa. Clean the Alpha-Stim® AID by gently wiping the surface with a damp cloth when dirty. Use mild soap and water if necessary. Use of other cleaning solutions may damage the case. Never spray cleaners directly on the device. 70% isopropyl alcohol may be used on the Earclip electrodes to disinfect them between treatments.

Trouble Shooting

Problem	Possible Solutions
There is no sensation of current. *Note: This is normal for some people.*	Try increasing the current or wetting EEP electrodes with more Alpha Conducting Solution™ (ACS™).
There are no results.	1. Treat more often or for a longer time at a lower current. 2. Some people require up to 3 weeks or more of treatment to begin to see an effect. 3. Consult your health care practitioner, authorized Alpha-Stim® distributor, or EPI for advice.
Electrodes do not stick well.	Make sure the Earclips are clean and dry before applying EEPS.
The ⊘ symbol appears.	1. Make sure Earclips are touching skin firmly. 2. Make sure the plug/jack connection is firmly in place. 3. Try wetting EEPS with more ACS™ 4. Change the batteries if they are low.

SERVICE

The Alpha-Stim® AID is not user serviceable.

To obtain service, first contact your authorized Alpha-Stim® distributor or Electromedical Products International, Inc. for advice. If necessary send the entire device, with all accessories, packed in the original case, if available, to:

Electromedical Products International, Inc.
2201 Garrett Morris Parkway
Mineral Wells, TX 76067-9034 USA

Send it insured, freight prepaid, and include a copy of your invoice and a note describing the problem. Please do not forget to include your return address, including country, and your phone number, and if you have them, fax and email.

5 YEAR LIMITED WARRANTY

While in the opinion of Electromedical Products International, Inc., ("EPI") the Alpha-Stim® AID ("Product") is generally effective in relieving anxiety, insomnia and/or depression, health care is not an exact science and individual results will vary. Accordingly, EPI makes no warranties as to the effectiveness of its Products for a given individual.

Electromedical Products International, Inc. warrants to the original purchaser (and no one else) that each new Alpha-Stim® AID is free of defects in workmanship and materials under normal use for a period of 5 years from the original purchase date, except for accessories. The warranty registration card must be completed and returned to validate the warranty.

Accessories such as batteries and electrodes are excluded from the warranty and are sold "as is" because they may be easily damaged before or during use.

During the warranty period, EPI's sole obligation shall be, at EPI's option, to replace or repair the Alpha-Stim® AID without charge. In order to recover under this warranty, purchaser must first contact EPI by phone,

mail, fax, or email to obtain a Return Material Authorization number (RMA). Purchaser must have a copy of the original invoice to prove that the Product is still covered by warranty. The authorized return may then be shipped to EPI safely packaged with freight and insurance prepaid. EPI will not be responsible for damage due to improper packaging or shipment. If EPI determines there is a defect covered by this warranty**,** the repaired or replaced Product will be shipped back freight and insurance prepaid as soon as reasonably possible. If EPI determines in its sole discretion that the Product does not contain defective workmanship or materials, EPI will return the Product and bill for the return freight and insurance charges.

This warranty is voided immediately if the Product has been subjected to abuse, accidental damage, damage in transit, negligence, acts of nature, damage resulting from failure to follow operating instructions, or alteration/disassembly by anyone other than EPI.

Electromedical Products International, Inc. shall not be liable for any direct, indirect, special, incidental, or consequential damages, lost profits or medical expenses caused by any defect, failure, malfunction, or otherwise of the Product regardless of the form in which any legal or equitable action may be brought against EPI (such as contract, negligence, or otherwise). In no event shall EPI's liability under any cause of action relating to the Product exceed the purchase price of the Product.

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